K083151

510(k) Summary of Safety and Effectiveness:

JAN 22 2009

EXTREMITY MEDICAL Implant System

Submitter	EXTREMITY MEDICAL LLC 300 Interpace Parkway Suite 410 Parsippany, NJ 07054
Contact Person	Jamy Gannoe President Phone 973-588-8980 Email jgannoe@extremitymedical com
Date Prepared	December 18, 2008
Trade Name	EXTREMITY MEDICAL Suture Anchor
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888 3040
Product Code	MBI
Predicate Devices	1 Orthopaedic Biosystems Ltd , Inc (Smith & Nephew) TwinFix Ti 2 8 Suture Anchor K972326 2 Smith & Nephew TwinFix PK FP Suture Anchor K073509
Device Description	The EXTREMITY MEDICAL Suture Anchor
Indications for use	The Extremity Medical Suture Anchor is intended for the fixation of suture and/or soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow in the following procedures *Shoulder* Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift of Capsulolabral Reconstruction *Foot/Ankle* Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot

	reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy *Knee* Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis *Hand/Wrist* Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction *Elbow* Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction
Statement of Technological Comparison	The EXTREMITY MEDICAL Suture Anchor and its predicate devices have the same indications for use have a similar design and are made of the similar materials
Conclusion	The EXTREMITY MEDICAL Suture Anchor is substantially equivalent to its predicate devices This conclusion is based upon the fact that this device is substantially equivalent in terms of indications for use, materials, design and principles of operation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Extremity Medical, LLC
% Mr Jamy Gannoe
President
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Parsippany, New Jersey 07054

JAN 22 2009

Re K083151
Trade/Device Name EXTREMITY MEDICAL Suture Anchor
Regulation Number 21 CFR 888 3040
Regulation Name Smooth or threaded metallic bone fixation fastener
Regulatory Class II
Product Code MBI
Dated October 22, 2008
Received October 24, 2008

Dear Mr Gannoe

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083151

Device Name EXTREMITY MEDICAL Suture Anchor

Indications for Use

The Extremity Medical Suture Anchor is intended for the fixation of suture and/or soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in the following procedures

Shoulder Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift of Capsulolabral Reconstruction

Foot/Ankle Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction

Elbow Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

Prescription Use X **AND/OR** **Over-the-counter** ____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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